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10/534,238	12/02/2005	Evgeny Evgenyevich Fesenko	U 015763-7	2731

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EXAMINER	
MITRA, RITA	

ART UNIT	PAPER NUMBER
1656	

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01/04/2008	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

Application No.

10/534,238

Applicant(s)

EVGENY FESENCO

Examiner

Rita Mitra

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 23 August 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 37-54 is/are pending in the application.
- 4a) Of the above claim(s) 45-54 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 37-44 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- 1) ☒ Certified copies of the priority documents have been received.
  - 2) ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION*****Election/Restrictions***

Applicants' response to Restriction Requirement mailed April 23, 2007, filed August 23, 2007 is acknowledged. Applicants have elected with traverse Group IV, claims 34-36 (new claims 37, 38, 39). Claims 1-36 have been cancelled. New claims 37-54 have been added. The traversal is on the ground(s) that as the DNA/amino acid sequences are recited in each of the claims as amended such that the claims define a single general inventive concept and the product human peroxiredoxin fragment (Delta.PrxVI hum) and its use is novel and nonobvious because claims include a feature that defines a contribution over prior art. This is not found persuasive because the inventive compound was known at the time this application was filed (see Fujjii et al, Eur. J. Biochem, 268 (2), pp 218-224, Jan, 2001, cited in Restriction Requirement). The reference describes expression of peroxiredoxin VI in rat lung and kidney after birth implies an antioxidative role. Persons skilled in the art could easily select different species of peroxiredoxin (PrxI- PrxVI) as the peroxiredoxin in the reference, and clone the DNA that encodes the peroxiredoxin protein and prepare the protein by expressing the DNA of SEQ ID NO: 3 that encodes an amino acid sequence of SEQ ID NO: 2. Moreover, persons skilled in the art could easily predict the effect of the use of the product. This renders the invention of claims 41-44 obvious over the prior art. Accordingly, the claims are not so linked by a special technical feature within the meaning of PCT Rule 13.2 so as to form a single inventive concept and lack of unity is deemed proper and is therefore made FINAL.

***Status of the Claims***

Upon further consideration composition claims 41-44 and method claim 40 have been rejoined for the current examination. Claims 45-54 are withdrawn from further consideration by the Examiner, 37 CFR 1.142(b) as being drawn to a non-elected invention. Therefore, claims 37-44 are currently under consideration.

***Specification Objections***

The disclosure is objected to because of the following informalities:

- 1) The continuity data has not been entered at page 1, line 1 of the specification.
- 2) The use of trademark has been noted in this application. GenBank™ D14662 has been noted on page 4, for example. They should be capitalized wherever it appears and be accompanied by the generic terminology. In this instance, the trademark/trade name is used to identify/describe PrxVI hum HA0683 cDNA. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner, which might adversely affect their validity as trademarks. The entire specification should be checked.

A correction is required.

***Claim Objections***

Claims 41 and 42 are objected to because of the following informalities:

1. Claim 41 is objected to because of a typo error. The word “of” between human and peroxiredoxin DELTA.Prx. VI should be deleted.

Appropriate correction is required.

***Claim Rejections - 35 U.S.C. § 112, Second Paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 37-44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 41 is rendered indefinite by the phrase “peroxiredoxin DELTA.Prx. VI hum of SEQ ID NO: 3.” It is not clear that how this protein fragment’s sequence is set forth in SEQ ID NO: 3 because SEQ ID NO: 3 has DNA sequence. A correction to read “peroxiredoxin DELTA.Prx. VI hum encoded by SEQ ID NO: 3” would overcome this rejection.

Claim 41 is also rejected because the claim does not recite the activity of the active fragment.

Claim 42 is rendered indefinite by the phrase “peroxiredoxin VI of SEQ ID NO: 1.” It is not clear that how this protein’s sequence is set forth in SEQ ID NO: 1 because SEQ ID NO: 1 has DNA sequence. A correction to read “peroxiredoxin VI encoded by SEQ ID NO: 1” would overcome this rejection. Claims 43 and 44 are included in the rejection because they depend from rejected claim and do not correct the deficiency of the claim from which they depend.

***Claim Rejections - 35 USC § 102***

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The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 37-44 are rejected under 35 U.S.C. 102 (b) as being anticipated by Fujii et al.

(Eur. J. Biochem. Vol. 268, pp 218-224, 2001) and Kang et al. (The J. of Biol. Chem., Vol. 273, No. 11, pp 6303-6311, March 13, 1998)

Fujii et al. teach an augmented expression of Peroxiredoxin VI (PrxVI) in rat lung and kidney, that has antioxidative role. The reference also teaches the cloning and sequencing of rat PrxVI cDNAs, and characterization by peroxidase assay, Northern Blot and Western Blot analysis and immunohistochemistry. (see abstract: page 218, col. 2, paragraph 2; page 219-220; Fig. 1, 2, 3 and 4). The Northern Blot and Western Blot result shows the tissue distribution of the protein (Fig 3) where the lung exhibited the highest level of both the protein and mRNA. The amino acid sequence of the protein indicates the presence of single conserved cysteine residue which is the characteristic of only PrxVI family (1-cys group), thus anticipating claims 37-40, which require an isolated nucleic acid molecule encoding a polypeptide comprising a fragment of PrxVI protein having an amino acid sequence of SEQ ID NO: 2. The amino acid sequence of the protein of Kang (see the rejection *infra*) shows 100% sequence identity to SEQ ID NO: 2 of instant application, thus the protein of Fujii inherently has the function of the Prx.VI protein. Further Fujii reference describes under Experimental Procedures (page 219-220) that the isolated protein was taken in water or suitable buffer during some steps of the procedure, thus anticipating claims 41-44 of instant application.

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Kang et al teach a mammalian peroxiredoxin that contains one conserved cysteine at position 47 (see Fig. 1). The recombinant human 1-Cys Prx mediates the reduction of hydrogen peroxide with the use of electrons from a nonphysiological donor DTT, and have a peroxidase function (see page 6303, Col. 2, Fig. 2 and 5). The peroxiredoxin protein of Kang that has 100% sequence identity to SEQ ID NO: 2 of instant application (see SEQ ID NO: 2 sequence alignment, result 1, database: UniProt\_8.4), thus anticipating claims 37-40 of instant application. Claim 1 of instant application requires an active fragment of SEQ ID NO: 2, which would be any fragment having any number of residues for example 1) fragment with only Glycine, which is known as a biologically active residue; 2) fragment containing amino acid sequence from position 2 to position 224 of SEQ ID NO: 2; 3) full length sequence of SEQ ID NO: 2 (see sequence alignment result); 4) fragment containing a C-terminal string of amino acids which can also be called as active fragment (see SEQ ID NO: 2 sequence alignment, result 10, database: UniProt\_8.4), thus anticipating claim 37.

### ***Conclusion***

No claim is allowed.

### ***Inquiries***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rita Mitra whose telephone number is (571) 272-0954. The examiner can normally be reached on M-F, 10:00 am to 7:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Kathleen K. Bragdon can

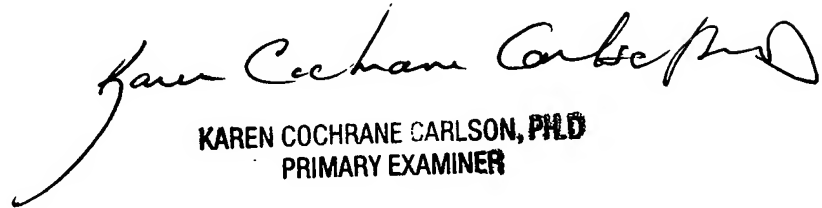
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be reached on (571) 272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Rita Mitra, Ph. D.

November 8, 2007



**KAREN COCHRANE CARLSON, PH.D.**  
**PRIMARY EXAMINER**